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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/500,246 02/08/00 FOSTER

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EXAMINER

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CHOI, F

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

07/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Applicant N .

09/500,246

Applicant(s)

FOSTER ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-15 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-15,17 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-15, 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. Pat. 5,288,496) in view of Herbert et al. (U.S. Pat. 5,654,008) and Okada et al. (4,652,441) for the reasons of record set forth in the prior Office Action and the further reasons below.

Lewis, Herbert et al. and Okada et al. were discussed in the prior Office Action and the same are incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant argues that no prior art reference has melengesterol acetate.

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However, the prior art teaches melengesterol, as such, one of ordinary skill in the art would expect that similarly structured derivatives would also be as effective as a hormone.

Applicant asserts that use of microparticles as delivery vehicles do not comprise any aspect of the claimed invention and that these delivery vehicles are nowhere suggested nor disclosed in the prior art reference. However, the limitations cannot be so narrowly interpreted. For instance "encapsulants" does not exclude microparticles nor is there anything in the body of the claim which appears to exclude microparticles as falling within the scope of the limitations set forth in the claims.

Contrary to Applicant's arguments, the prior art teaches both immediate and long-term release, as such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to have both so as to effect an immediate treatment or relief and treatment or relief over a period of time. (See Lewis, Column 6, lines 43-55, Herbert et al., Column 17, lines 47-55). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., discrete particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 26 USPQ2d 1057 (Fed. Cir. 1993).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1, 4-7, 10, 13-15, 17, 18, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. for the reasons of record set forth in the prior Office Action and the further reasons below.

Stevens et al. was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's argument that the prior art reference fails to discuss the differential release of the same active ingredient, the test for obviousness is not whether the invention must be expressly suggested in the reference. Rather, the test is what the combined teachings of the reference would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Herein, the cited reference teaches the preparation of immediate release and controlled-release pellets and that different pellets may be administered at the same time. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use both with the expectation of obtaining immediate treatment or relief or an initial burst combined with extended treatment to cover any infection or condition which the immediate release pellet does not meet conveniently in a single injection.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 1, 6-10, 13, 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rickey et al. for the reasons of record set forth in the prior Office Action and the further reasons below.

Rickey et al. was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's argument that the prior art reference fails to discuss the differential release of the same active ingredient, the test for obviousness is not whether the invention must be expressly suggested in the reference. Rather, the test is what the combined teachings of the reference would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Herein, the cited reference teaches the preparation of immediate release and controlled-release pellets and that different pellets may be administered at the same time. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use both with the expectation of obtaining immediate treatment or relief or an initial burst combined with extended treatment to cover any infection or condition which the immediate release pellet does not meet conveniently in a single injection. Further, as indicated above, the claims do not appear to exclude microparticles.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 1, 4-7, 10, 13-16, 17, 18, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al. for the reasons of record set forth in the prior Office Action and the further reasons below.

Guittard et al. was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's argument that the prior art reference fails to discuss the differential release of the same active ingredient, the test for obviousness is not whether the invention must be expressly suggested in the reference. Rather, the test is what the combined teachings of the reference would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

Herein, the cited reference teaches the preparation of immediate release and controlled-release pellets and that different pellets may be administered at the same time. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use both with the expectation of obtaining immediate treatment or relief or an initial burst combined with extended treatment to cover any infection or condition which the immediate release pellet does not meet conveniently in a single injection.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

July 9, 2001

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1600

